PRODUCT PERFORMANCE/EFFICACY REVIEW

BY

Kevin J. Sweeney, Entomologist, IB

Kevin Sweeney 3/2/04

Date: March 2, 2004

Reviewer: George LaRocca

PM: PM 13, George LaRocca

Product Reg. No: 73510 -2 and 73510-L

Product Names: Marketquest One Drop Flea & Tick Control
Marketquest One Drop Flea and Tick Control with IGR

Decision # 331704 and 331701

DP: 293541 and 295707

OPPTS Guideline: 810.3300

Chemical: permethrin 45% (-2 product)
Permethrin 45% and S-methoprene 1.2% (-L product)

Use pattern: RTU spot-on for dogs

Accepted Application rate: -2 product (3/1/02 accepted label)
Apply 1.5 ml per dog **(33 lbs. or less) every 4 weeks**.
Apply 3.0 ml for dogs (33 lbs or more) every 4 weeks.
No directions for larger dogs

Proposed application rates -2 amendment and - L product
Apply 1.0 ml per dog (15 lbs. or less) every 4 weeks.
Apply 1.5 ml per dog (15 to 33 lbs.) every 4 weeks.
Apply 3.0 ml per dog (33 to 66 lbs.) every 4 weeks.
Apply 4.5 ml per dog (> 66 lbs.) every 4 weeks.

Accepted Pests: kill/repel fleas and ticks

Proposed pests:
-2 and -L
Kills/repels fleas and ticks.
Kills mosquitoes.
Protects against mosquitoes (vectors of heartworm). Also kills and repels deer ticks and

brown dog ticks.

-L only stops flea eggs from hatching

Submitted Studies and Method of Support:

The method of support for product performance appears to be the selective method (or cite all option) and the following product performance studies were submitted.

MRID 46039501 Efficacy evaluation of a permethrin squeeze-on against adult cat fleas, adult brown dog ticks, nymphal deer ticks, and *Aedes aegypti* mosquitoes.

The submitted data tested the reduced application rate for small dogs under 15 lbs and large dogs over 66 lbs. when compared to previously accepted permethrin studies for spot-on labels. The data were quite variable between test groups and between post-treatment test days. A consistent product performance trend was not always evident. In addition, 6 animals were used for the dogs in the lower weight ranges but only three in the upper weight ranges. The small sample size probably contributed to the variability of the results.

MRID 46041303 Dose Titration of an s-methoprene Spot-on Dogs. Final Report, Statistical Analyses and Conclusions.

The study used only 2 dogs per treatment and did not test the range of animal weights listed on the product label. This is not even close to a OPPTS 810.3300 guideline study. The study seems like confirmatory data but no additional studies are cited for methoprene in the data matrix other than this one.

Entomologist Recommendation and Comments:

1. Based on the data submitted, the use of less than 1.5 ml of product on dogs 15 lbs. or less is not acceptable. The reduction of volume for larger animals was not acceptable either. The data were too inconsistent. Also, small dogs were not tested with s-methoprene at the proposed volume.

2. In addition, the currently accepted label for 73510-2 should add separate directions for large dogs as was the case for the original labels submitted in 2001. In Vern McFarland's review from June 2001, he noted that 6.0 ml should be applied to large dogs weighing more than 66 lbs. Four weight ranges were listed and Mr. McFarland reviewed labels and accepted them. The customary treatments remained on pending labels through November 16, 2001 but in February 2002, the labels were changed and ultimately were approved in March 2002 using only two dog weight ranges. This resulted in a product applying less permethrin to a dog than the other products in the industry without submitted or cited product performance data. The data submitted with the current amendment do not support the lower dose labeling claims.

3. The mosquitoes claims are unacceptable for both products. The % kill was too low and many mosquitoes were feeding, therefore, the product did not repel mosquitoes or protect the dog from mosquito bites, disease vectors, or diseases. For instance, in the control, the mean on Day 8 was 18 blood fed mosquitoes while one treatment had 11 blood fed mosquitoes and the other 6.

4. Generally, the efficacy of the product should be evaluated at the 24 hour post-treatment interval, not at 48 or 72 hours. Evaluation of longer exposure times can be helpful sometimes but the spot-on should have repelled or killed the arthropod at 24 hours. In the submitted studies, the product failed after 16 days for small dogs under 15 lbs. (see table 12) for both flea and tick control and failed by three weeks for all treatment groups. The data only support an "up to 3 week" claim for all dog groups except those below 15 lbs. These data were not supportive of four weeks control. The registrant appears to have made an offer to pay to retain the 4 week control claim but it is unclear if this included product performance data (supported by the selective method?) because they submitted studies and listed them on the data matrix.

5. The claim for *Ixodes scapularis*, the deer tick or blacklegged tick, is not acceptable.